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REGULATORY REQUIREMENTS FOR VENTILATORS AND RELATED ACCESSORIES

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REGULATORY REQUIREMENTS FOR VENTILATORS AND RELATED ACCESSORIES

Options for supporting production and/or placing on the market of ventilators in the context of COVID-19 pandemic

1. INTRODUCTION AND SCOPE

The World Health Organization (WHO) declared the COVID-19 outbreak a pandemic on March the 12th 2020. Patients infected by SARS-CoV-2 virus and developing the COVID-19 disease with acute and severe respiratory symptoms have to be treated with mechanical ventilators to assure possibilities of survival.

This guidance document focuses on ventilators and related accessories that are currently regulated under the Council Directive 93/42/EEC (MDD)[1]. According to the MDD, devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose[2].

The devices must meet the essential requirements set out in Annex I of the MDD, which apply to them, taking account of the intended purpose of the devices concerned. In addition, devices may be placed and circulate on the European single market if they have been subject to a conformity assessment in accordance with the provisions of Article 11 of the MDD.

Under the current COVID-19 context, the demand for ventilators and related accessories has rapidly increased. Therefore, this document intends to outline the different regulatory options for placing these devices on the EU market indicating their feasibility to allow short-term supply.

2. TYPES OF MEDICAL DEVICES AND THEIR PARTS/COMPONENTS

2.1. Ventilators

Ventilators are breathing support devices and can fall into different types according to their intended use and characteristics[3]:

[1] However, placing on the market of devices which comply with MDD is limited to 27 May 2024. After this date every device placed on the market has to comply with the requirements of Regulation (EU) 2017/745 (MDR). According to the Article 120 section 5 and 6 of the MDR devices which comply with MDR may be placed on the market before its application and notified bodies which are designated and notified in accordance with MDR may carry out the conformity assessment procedures laid down in MDR and issue certificates in accordance with MDR.

[2] According to Article 1(g) of the MDD, intended purpose is the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

[3] This list of ventilators includes some standards applicable to the specific ventilator. However, it should be noted that this is not an exhaustive list and other standards also apply to these devices and should be taken into account (e.g. EN 60601-1-2, EN 60601-1-6, EN 60601-1-8, EN 60601-1-11, EN 62304, EN 62366). In addition, the current state of the art should be considered. This applies also to accessories.

- **Ventilator for critical care:** automatic equipment that is intended to augment or provide ventilation of the lungs of the patient when connected to the airway of the patient:
    - intended for use in an environment that provides specialized care for patients whose conditions can be life threatening and who can require comprehensive care and constant monitoring in a professional healthcare facility;
    - intended to be operated by a healthcare professional operator; and
    - intended for those patients who need differing levels of support from artificial ventilation including for ventilator-dependent patients.

  (See e.g. EN ISO/IEC 80601-2-12:2011 + Cor.:2011).
- **Home healthcare environment ventilators for ventilator-dependent patients:** intended for use in the home healthcare environment; intended for use by a lay operator; intended for use with patients who are dependent on mechanical ventilation for their life support. Depending on the intended purpose can be also used in the clinical setting (See e.g. EN ISO 80601-2-72:2015).
- **Ventilators for emergency and transport:** these ventilators are used in Emergency Medical Service environment, e.g. in ambulances, transport of patients to the hospital, patient transport from hospital to hospital or transport within the hospital. The alarm and safety concept of emergency and transport ventilators in general is designed for a permanent presence of the user. This facilitates fast recognition and response in the event of an alarm or in the event of any malfunction (See e.g. EN 794-3:1998+A2:2009).
- **Anaesthetic ventilator:** are designed for use during anaesthesia with an anaesthetic breathing system (See e.g. EN ISO 80601-2-13:2012).

Ventilators for critical care are usually invasive, which enables the ventilator machine to provide lung support for inspiration and expiration through tracheal intubation. However, most critical care ventilators allow non-invasive ventilation modes for critical care patients as well. Ventilators for non-critical care are usually non-invasive and therefore provide air pressure support to natural breathing through e.g. a facemask.

Ventilators may offer different types of additional complementary functions that include:

- High flow oxygen supply (nasal high flow therapy);
- Monitoring systems;
- Nebulisation systems.

2.2. Accessories

Ventilators need to be "connected" to the patients through dedicated accessories[4] to the ventilator that allow the machine to support the patient's breathing; therefore, it is important to proof compatibility with the ventilator(s). These accessories can be placed on the market individually and usually fall into one of the following categories:

[4] See MEDDEV 2.1/1 Definitions of 'medical devices', 'accessory' and 'manufacturer' (https://ec.europa.eu/docsroom/documents/10278/attachments/1/translations).

- Breathing systems and circuits, such as:
  - Circuits;
  - Connections/Adapters;
  - Tubes;
  - Nasal cannulas for O_2;
  - Masks or helmets for non-invasive ventilation;
  - Air compressors;
- Nebulizers;
- Humidifiers and filters;
- Monitoring accessories, including alarms, in-built safety features.

Accessories are provided either disposable or reusable and are treated as medical devices in their own right[5].

2.3. Parts or components

Parts or components of medical devices that do not qualify as accessories are generally not considered medical devices and thus not requiring themselves to be CE marked according to the MDD (e.g. expiratory valves or flow sensors).

3. CLASSIFICATION

3.1. Ventilators

There are different types of ventilators depending on the degree of invasiveness and the setting in which they are used in (e.g. Intensive Care Unit - ICU). Ventilators fall under two different classes in accordance with rule 11 (or rule 9) of Annex IX[6,7] to the MDD:

- Class IIa: only applicable to non-invasive devices, e.g. continuous positive airway pressure – CPAP non-intended for critical care, or devices that only support spontaneous breathing.

- Class IIb: applicable to most ventilators.

The classification depends on the intended purpose of the ventilator and has important implications in the selection of appropriate conformity assessment procedure(s) for the device including timing and complexity (see section 4 for details).

3.2. Accessories

Accessories are classified in their own right usually in accordance with rule 2 or 5 of Annex IX to the MDD, under Class I, IIa or IIb.

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[5] Art. 1(1) of the MDD

[6] See MEDDEV 2.4/1 rev.9 Classification of Medical Devices - (https://ec.europa.eu/docsroom/documents/10337/attachments/1/translations).

[7] Please note that if a conformity assessment under the MDR is followed, the rules of classification specified in Annex VIII to the MDR apply. Breathing support devices may be classified to class IIa or IIb (rule 12) or class III (rule 22) if they integrate or incorporate diagnostic functions which significantly determine the patient management by the device, such as closed loop systems.

3.3. Impact of classification on conformity assessment

Given that ventilators are classified as Class IIa or Class IIb, and accessories (except for Class I non-sterile and without measuring function), will in principle need the involvement of a notified body prior to their placing on the market. Other options for the placing on the market are provided in section 4 for both ventilators and accessories.

4. REGULATORY OPTIONS FOR PLACING VENTILATORS ON THE MARKET

In the context of the COVID-19 outbreak, several industries have expressed their willingness to support and scale up the production of ventilators[8]. There are different regulatory options[9] available for supporting production or placing on the market of ventilators. These options are presented below, ordered by feasibility, to allow a swift supply in the current context.

4.1. Supplying parts, components or the finished devices to medical devices manufacturers currently placing on the market ventilators

When the legal manufacturer[10] has already undergone a conformity assessment for the ventilator, has obtained a certificate and is lawfully placing ventilators on the market under its own name, other producers (e.g. not currently working in the medical devices field) can support its production. Such producers can provide parts or components, or the finished device, therefore becoming suppliers or subcontractors of this manufacturer.

Given that the medical devices sector is highly regulated and complex, leveraging the knowledge and responsibilities of an already established manufacturer of ventilators could be the least burdensome and fastest option to scale up the production of ventilators.

4.1.1. Producers supplying parts or components to medical devices manufacturers currently placing on the market ventilators

Manufacturers of medical devices can have many suppliers, which in case of quality system certification are qualified, approved and controlled by the manufacturer. These suppliers may need to be assessed by a notified body as part of the conformity assessment procedure on the basis of their criticality and the manufacturer's process in place to control suppliers and the verification of purchased products[11]. When the manufacturer wishes to use an additional supplier, this might need to be communicated in advance to the notified body.

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[8] Scaling up of production might also be needed for accessories. These medical devices can follow the same options explained in section 4 but small differences can be applicable in case they have a different classification (e.g. class Is).

[9] This document mainly focuses on regulatory options provided by the MDD. If a conformity assessment under the MDR is followed, similar procedures will apply under Annex IX, X or XI of the MDR depending on the classification of the product.

[10] Legal manufacturer refers to the definition of manufacturer established in Art. 1(f) of the MDD.

[11] See Guidance for Notified Bodies auditing suppliers to medical device manufacturers – (http://www.doks.nbog.eu/Doks/NBOG_BPG_2010_1.pdf)

4.1.2. Producers manufacturing the ventilator itself for the medical device manufacturer currently placing on the market ventilators

Manufacturers of medical devices producing ventilators may provide the specifications of a ventilator (e.g. current or older/simpler design) including parts of the technical documentation to a producer that becomes its subcontractor. The producer will manufacture the ventilator but the medical device manufacturer will keep its role of legal manufacturer according to the MDD.

The legal manufacturer of the ventilator, which holds a quality system certification, qualifies, approves and controls the subcontractor that will need to be assessed by a notified body as part of the conformity assessment procedure. When the manufacturer wishes to use an additional subcontractor, this will need to be communicated in advance to the notified body (i.e. as the subcontractor is considered critical[11]) that will assess the available information and will decide the actions to be put in place e.g. whether or not it is necessary to carry out an (on-site[12]) audit.

Alternatively, the manufacturer of medical devices could also follow other conformity assessment routes such as the EC type-examination, as established in Annex III to the MDD, and/or EC verification, as established in Annex IV to the MDD (these routes are elaborated in 4.3.2).

4.2. Derogation procedure – placing on the market authorised by the relevant authorities of one Member State in the interest of public health

The relevant authority of one Member State may decide to authorise the placing on the market of devices in the interest of protection of health, even if the applicable conformity assessment procedures have not been finalised or initiated ('national derogation').

In view of the epidemiological context as well as the exponential growth in demand for medical devices, the Commission has published a Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the Covid-19 context.

Question 5 of this guidance provides information on the derogation procedures for medical devices which is established in Article 11(13) of the MDD. In particular, the guidance specifies that the Covid-19 context warrants the application of such derogations.

By amendment of 23 April 2020[13], Article 59(1) of Medical Devices Regulation (EU) 2017/745 (MDR) empowers Member States to adopt national derogations under both the MDD and the MDR from the date of entry into force of that amendment.

The relevant competent authority of the Member State in this case authorises the placing on the market within its territory and can also organise the purchase.

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[12] See MDCG 2020-4 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions (https://ec.europa.eu/docsroom/documents/40705).

[13] Regulation 2020/561 amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions.

In practice, this implies that each competent authority would need to assess whether the products produced by the manufacture provides an adequate level of safety in respect to the applicable legal requirements. The assessment procedures can vary among Member States and in some cases will involve the support of third parties (e.g. testing laboratories).

In the exceptional COVID-19 context, the assessment procedures will ensure a short-term supply while guaranteeing patient safety[14]. The Member State will evaluate the available technical documentation to find evidence that essential performance and safety requirements are guaranteed in the context of use. In particular, the role of healthcare teams and health facilities is essential to allow a rational use and a continuous assessment of these crisis solutions.

Once this assessment is performed, the authority has to take a decision, whether or not the respective device produced by the manufacturer may enter the national territory of the Member State. Competent authorities should inform the Commission and their counterparts in other Member States of any temporary agreement they have granted to specific devices.

In addition, Article 59(3) of the MDR empowers the Commission to extend, in exceptional cases relating to public health or patient safety or health, by means of implementing acts, for a limited period of time the validity of a national derogation, granted by a Member State under the MDD or the MDR, to the territory of the Union and set the conditions under which a device may be placed on the market or put into service. This allows the Commission and the Member States to address potential shortages Union wide of vitally important medical devices in an effective manner.

Timing to obtain a national derogation by a competent authority will greatly depend on the quality and adequacy of the evidence provided by the manufacturer. When technical documentation and evidence of safety of performance is adequate, this can be a feasible option to ensure short-term supply.

4.3. Manufacturing of the finished device by a producer that was not previously placing on the market ventilators

If the ventilator is entirely manufactured by a producer that decides to place it on the market under its name, such producer will become the legal manufacturer in its own right. This means that the manufacturer will need to fulfil all requirements of the MDD (e.g. including the need to draw up the technical documentation and clinical evaluation related to the ventilator, and to establish and keep up to date a systematic procedure to review experience gained from devices in the post-production phase).

The manufacturer who places the finished CE marked ventilator on the market under its own name needs to ensure that the device complies with the essential requirements (established in Annex I of the MDD) and provide relevant evidence. A notified body will be involved in the conformity assessment in all cases.

[14] Some Member States have published guidance on their respective websites to support this assessment e.g. in case of implementation of innovative manufacturing processes such as 3D printing.

Given that the medical devices sector is highly regulated and complex, the scenarios presented below will be the most burdensome and therefore only applicable to increase supply in the medium-long term.

4.3.1. Medical devices manufacturers' not currently producing ventilators request an extension of their product range.

This option is available for medical devices manufacturers currently certified. It includes, for instance, medical devices manufacturers already holding a full quality management system certificate under Annex II to the MDD for other devices and wishing to add ventilators to their certification. They could seek the support from (non-medical devices) producers to act as subcontractors and extend the scope of their certificate.

From a procedural point of view, the medical devices manufacturer may produce the ventilator itself or may utilise a subcontractor (i.e. producer linked or not to the medical devices field). In the latter case, the manufacturer will qualify, approve and control the subcontractor that will be assessed by the notified body as part of the conformity assessment procedure. When the manufacturer wishes to use an additional subcontractor, this will need to be communicated in advance to the notified body (i.e. as the subcontractor is considered critical[11]) that will assess the available information and will decide the actions to be put in place e.g. whether or not it is necessary to carry out an (on-site[12]) audit.

Most importantly, the manufacturer will need to request an extension of the product range from its notified body. The notified body will assess the available information in relation to the new product (that include an assessment of the technical documentation and clinical evaluation) and update the certificate.

The manufacturer of medical devices could also use other conformity assessment routes such as the EC Type-Examination and EC Verification and testing of every product under Annex III and IV respectively (these routes are elaborated in section 4.3.2).

4.3.2. Ventilator manufactured entirely by a producer that is not currently a legal manufacturer under the MDD

Producers that do not currently qualify as legal manufacturers under the MDD and decide to place ventilators on the market under their own name need to be aware of all the legal requirements for manufactures under the MDD. It is important to mention that in the field of medical devices some Member States could have additional requirements, for instance, the need to authorise the facility of the medical device manufacturer prior to starting production.

In addition to this, the involvement of a notified body will depend on the classification. In particular:

1. Class IIa ventilators can follow the following routes established in the relevant Annexes of the MDD:
    a. Annex II (excluding point 4) – which involves the assessment of the full manufacturer's quality management system. This will require an on-site audit (which may be performed remotely in the current context) and

regular surveillance audits at least annually. In addition, the notified body will assess the technical documentation and the clinical evaluation of the product to be certified prior to certification on a sampling basis[15].

b. Declaration of conformity (Annex VII) combined with either an assessment of the quality assurance of the production or of the product (Annex V or VI) or a EC verification (set out in Annex IV):
    - The assessment of the quality system performed by the notified body will be similar to the one outlined in section 1.a above.
    - The verification by testing of products by the notified body will be performed by examination and testing of every product.

2. Class IIb ventilators can follow the following routes:
    a. Annex II (excluding point 4) – which involves the assessment of the full manufacturer's quality management system. This will require an on-site audit (which may be performed remotely in the current context) and regular surveillance audits at least annually. In addition, the notified body will assess the technical documentation and the clinical evaluation of the products to be certified prior to certification on a sampling basis[15].
    b. EC type-examination (Annex III) combined with either an assessment of the quality assurance either of the production or of the product (Annex V or VI) or EC verification by testing of products (set out in Annex IV). EC Type-examination consists in the assessment of the technical documentation and testing of a number of features of the device type to ensure it conforms to the requirements. The additional procedures (Annex IV, V or VI) are the same as the ones described in 1.b above.

The assessment of the quality management system of the manufacturer (Annex II, V and VI) can be partly fulfilled by compliance with a harmonised standard (EN ISO 13485) but this route will unlikely be fast enough to ensure short-term supply. This is due to the timelines and experience required to get a certificate under these annexes of the MDD and taking into account the current circumstances where auditing capacity is restricted by the Covid19 situation.

A faster route but also time-consuming route will probably be the performance of tests on the products that might be combined with the assessment of the technical documentation, namely:

- declaration of conformity (Annex VII) + verification of products (Annex IV) for Class IIa; or
- EC type-examination (Annex III) + verification of products (Annex IV) for Class IIb.

Through this route, the device type or device samples are tested and there is no obligation to have a certified quality management system in place and subject to regular surveillance audits. However, quality management processes are important and critical to the production of safe and functional medical devices. The conformity assessment will be

[15] See Annex II, section 3.3 to the MDD

based on the manufacturers testing strategy that must ensure compliance with the safety and performance requirements.

It should be noted that this option is burdensome and will take several months, especially to draw up an adequate technical documentation. In addition, there is only a limited number of notified bodies designated to perform EC type-examination and/or EC verification in ventilators (according to NANDO[16] 18 notified bodies out of 56 are authorised to perform these tests at the moment).

[16] This information can be found in NANDO, by searching notified bodies under the MDD that are designated under Annex III and IV for code MD 1102 - Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia -

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13